REVIEW ARTICLE



Emerging next-generation robotic colonoscopy systems towards painless colonoscopy

Chung-Kwong Yeung^{1,2} | Jo LK Cheung¹ | Biji Sreedhar¹

¹Bio-Medical Engineering (HK) Limited, Hong Kong SAR, China

²Department of Surgery, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong SAR. China

Correspondence

Chung-Kwong Yeung, Bio-Medical Engineering (HK) Limited, Units 401-404, Core C, Cyberport 3, 100 Cyberport Road, Hong Kong SAR, China.

Email: ck.yeung@nisi.hk

Advances in the field of robotics have allowed modern technology to be integrated into medicine and that can minimize patients suffering from the side effects that are inherent to procedures for improving their quality of life. Conventional devices that are used for colonoscopies are rigid and require a high level of expertise from endoscopists to perform the procedure. Advances in robot-assisted colonoscopic systems now produce softer, more slender, automated designs that no longer require the operator to use forceful pushing to advance the colonoscope inside the colon, reducing risks to the patient of perforation and pain. It is challenging to reprocess these scopes for reuse as the materials used can be damaged during decontamination, leading to the possible risks of cross-infection by pathogenic microorganisms when reused by patients. An ideal solution is to eliminate these contamination risks to patients by adopting sterile, single-use scopes straight from the manufacturer's package to the patient.

With this idea in mind, emerging developments that push the boundaries in this area will benefit patients and encourage the public to participate in and adhere better to colonoscopy screening to reduce the development of colorectal cancer. Thus, in light of these concerns and challenges, to encourage patients undergoing colorectal screening to comply with colonoscopy procedures that they are less invasive, changes in the design and materials are necessary. One of the more promising technological advances in this area is the advent of robotic colonoscopy.

KEYWORDS

colonoscopy, colorectal cancer, new technology, robotics

1 | COLORECTAL CANCER (CRC) AND SCREENING

Worldwide, CRC is a leading cause of morbidity and mortality ranking third as the most common cancer and fourth in cancer-related deaths, with approximately 1.8 million new cases representing 10.2% of all cancers, and 880 792 deaths (9.2%) in 2018. More than 55% of the new cases occur in developed countries with up to a 10-fold variation in incidence. In recent years, an increase in incidence and mortality

rates from CRC has been seen in medium to high human development index countries, indicating its high correlation with rapid societal and economic changes and a western lifestyle. Arnold et al reports that the global burden of CRC is expected to increase by 60% to more than 2.2 million new cases and 1.1 million deaths by 2030.²

Conventional colonoscopy is the method of choice for CRC screening and has been the gold standard for the past 40 years. Since the human colon is a tortuous tube with many sharp bends, the insertion of this endoscopic instrument is technically demanding and

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2019 The Authors. Journal of Digestive Diseases published by Chinese Medical Association Shanghai Branch, Chinese Society of Gastroenterology, Renji Hospital Affiliated to Shanghai Jiaotong University School of Medicine and John Wiley & Sons Australia, Ltd

196 wileyonlinelibrary.com/journal/cdd J Dig Dis. 2019;20:196–205.

requires the use of force that can cause discomfort to the patient during the colonoscopic examination. Looping can also be formed during an examination which greatly increases the patient's pain³ and leads to incomplete colonoscopy procedures.^{4–6}

The long and asymptomatic course of natural pathogenesis from a precancerous polyp towards the development of invasive cancer provides a unique opportunity to screen for cancer at an early stage. Thus, the ability to detect polyps using a colonoscopic device is very important for CRC prevention. However, a significant number of polyps and adenomas (up to 30%)⁷⁻⁹ are missed during a conventional colonoscopic examination and most often these missed lesions are located in the proximal regions of the colon, at the flexures or behind the haustral folds of the colon, where they may be overlooked or in a location that makes it difficult for an endoscopist to detect, leading to the possible development of interval cancer. 10,11 More importantly. these missed lesions are often diminutive. ¹² Another rising concern is the possibility of transmitting infectious disease through reusing the endoscopes after reprocessing them. Studies have shown that reprocessing is ineffective and that residual pathogens have been found. 13-15 With the aforementioned concerns and challenges, there is a need to make a less invasive colonoscopy procedure to which patients will be more compliant for improved colorectal screening, that is easy for endoscopists to use and is a single use instrument to eliminate cross-infections and to improve the rate of polyp detection. Changes in its design and materials are thus necessary.

2 | ADVANCES IN NON-ROBOTIC COLONOSCOPY

Several designs have previously been developed aimed to reduce the needs of forceful pushing to advance the colonoscope. These include wireless capsules such as the PillCam Colon (Medtronic, Minneapolis, MN, USA), which is an ingestible video capsule that has an operative time of approximately 10 hours. It has been reported initially that sensitivities in detecting polyps > 6 mm ranged between 50% and 70%, with specificities between 73% and 100%. However, in a later study, the sensitivity reached 89%, but with a disappointing specificity of 76%.¹⁷ Despite clearly achieving improvements in patients' comfort, the sensitivity of the test relies on good bowel preparation and the examination is limited to diagnostic use. The CathCam (Ethicon Endo-Surgery, Cincinnati, USA) is wire-guided catheter designed to minimize the effective push that is required on the shaft and to reduce looping and stretching of the colon. The CathCam is used with a 0.024-inch hinged lumen-seeking guidewire to negotiate bends. This guidewire is advanced through the accessory channel of the catheter into the lumen of the colon and guides the catheter forward when the catheter is pushed. The stiffness is 5-fold less than that of a colonoscope. In a study using live pigs, a 30% and 40% reduction in the peak force exerted on the colon was identified. 16 However, the CathCam system is an investigational device and has not been approved for clinical use. An alternative way of reducing invasiveness to the patient is to use virtual colonoscopy, also called computed tomographic (CT) colonography. This a radiological procedure in which thin helical sections of the colon are acquired on a CT scanner and multiple images are reconstructed to produce 2-D or 3-D images, resembling conventional colonoscopy and using imaging software. For optimal quality, good bowel preparation is crucial for the success of the procedure, as residual stool and fluids lead to a false diagnosis. The patient does not require sedation; however, as the colon is insufflated with air or gas to expand and distend the colon for a maximum view of the colonic wall, this may cause discomfort and pain. The limitations to this procedure include radiation exposure, prominent and complex folds of the colon and diverticular fold thickening, shifting of pedunculated polyps may be problematic in 2D imagery. An alternative approach that can allow the endoscopists to visualize the shape of the colonoscope is the ScopeGuide from Olympus (Tokyo, Japan), which uses electromagnetic tracking that can provide the real-time positioning of the rendered colonoscope inside the colon on a screen to inform the endoscopists if the colonoscope has formed any looping. 18

3 | ADVANCES IN ROBOTIC COLONOSCOPY

The other end of promising technological advances in this area is the advent of robotic colonoscopy. 19 To eliminate risks of cross-infection of the colonoscope between patient use, the scope ideally should be made to be of single use. Due to the complicated characteristics of the colon, the colonoscope has to be able to navigate and advance in a stretchable, slippery, and perhaps in a partially collapsed colon.²⁰ More importantly, a colonoscope that is designed to anchor itself to the colonic wall to flatten mucosal folds and provide better visualization of the colon will allow a more thorough examination for the presence of diminutive polyps or lesions. Locomotion in nature has led many researchers to develop bio-inspired colonoscopes that mimic, for example, the movements of the earthworm, snake, caterpillar and even microscopic cilia, the hair-like structures that are associated with motility that line the inner surfaces of the respiratory tract, middle ear, and other body systems. Thus, colonoscopes based on different modes of locomotion have been developed.

4 | ENDOTICS

The Endotics system (Era Endoscopy, Peccioli, Pisa, Italy) uses a lengthening and shortening concept that clamps to two anchor points to propel itself forward, a concept that was inspired by inchworm locomotion. The system is composed of a sterile disposable robotic head probe, a steerable tip, a flexible body and control box that contains an electro-pneumatic connector, and a workstation that allows the surgeon to control the endoscope by a handheld device. The robotic head is steerable at 180° in all directions and can elongate in a semiautomatic manner to move forward along the intestine. The sequence of locomotion is designed to move like an inchworm where two clampers anchored by a vacuum are located at the proximal and distal ends of the probe that sequentially extend and retract the



Adhesion of the proximal



Elongation and adhesion of the distal clamper



Release of the proximal clamper and shortening

FIGURE 1 Endotics sequence of locomotion using the inchworm mechanism (adopted with permission from Seah et al³⁴, 2017)

central body of the device¹⁸ (Figures 1 and 2). This suction and selfpropelling mechanism exerts low force during its movements as it adapts to the geometry of the human intestine.²²

Experiments using a phantom made of a plastic human abdomen together with a porcine colon to mimic the geometry of the human colon was used. One study used sensors attached to 3 points where the maximum stress level is usually detected during a conventional colonoscopy that is, sigmoid, splenic flexure, and hepatic flexure, demonstrated a 90% reduction in the application of force compared with the conventional colonoscope. However, when tested in 40 patients, the cecal intubation rate was only 27.5% compared with 82.5% in a conventional colonoscopy (Table 1).²² In a subsequent study comparing the Endotics system and a conventional colonoscope to detect

polyps in 71 patients with either a clinical or a history of familial risk of polyps, showed both methods had comparative diagnostic accuracy. All patients underwent tandem examinations on the same day. Overall, the cecum was reached more frequently using a conventional colonoscope (P = 0.03) than in the Endotics system. The procedural time was also longer for the Endotics system, which took 45.1 vs 23.7 min, $P \le 0.001$). However, patients using the Endotics system did not ask for sedation whereas in conventional colonoscopy, 14 patients (19.7%) asked for the administration of midazolam and meperidine for pain management.²³ The sensitivity and specificity of the Endotics system in the detection of polyps was 93.3% and 100%, respectively. The positive predictive value was 100% and the negative predictive value was 97.7%. The reduction in pain using the Endotics system was further demonstrated in another study where the Endotics system was compared in its diagnostic performance and tolerability in the staging of ulcerative colitis. In that study 12 patients with inflammatory bowel disease were enrolled, and a significant difference in pain reduction was seen in patients using the Endotics system.²⁴ In a more recent study, the authors analyzed retrospectively 276 Endotics examinations that were performed between January 2008 and December 2012. Of the 276 examinations, 102 procedures by conventional colonoscopy failed. The Endotics system was used to assess the rate of cecal intubation and was able to perform successfully in 93.1% of the incomplete conventional colonoscopy cases.²¹ At the time of study, the Endotics system was still a diagnostic tool and recently a working channel for biopsy has been implemented.²¹

5 | AER-O-SCOPE

This is a self-propelling, self-navigating and disposable colonoscope developed for diagnostic colonoscopy by GI View, Ramat Gan, Israel. It consists of an external workstation with a full joystick control and a disposable unit (Figure 3).³⁰ The disposable unit consists of 3 components: a rectal introducer, a supply cable and an endoscope that is embedded within a scanning balloon that together acts as the vehicle. The rectal introducer consists of a hollow silicon tube with an outer silicon balloon attached, which is inserted to the rectum. A supply







FIGURE 2 The Endotics system (adopted with permission from Seah et al³⁴, 2017 and Yeung et al³⁵, 2016) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Clinical data obtained from robot-assisted colonoscopes

	Partic	Participants			Cecal intubation rate n (%)	on rate n (%)	Cecal intubation time (min)	on time (min)	Requested sedation n (%)	lation n (%)	Pain score	
Study	z	Male n (%)	Female n (%)	Mean age (y)	Study device	Study device Conventional	Study device Conventional	Conventional	Study device	Study device Conventional	Study device	Conventional
Endotics												
Cosentino et al. $(2009)^{22}$	40		27 (67.5) 13 (32.5)	ı	11 (27.5)	33 (82.5)	57	ı	ı	ı	0.9 ^a	6.9ª
Tumino et al. ²³	71	40 (56.4)	40 (56.4) 31 (43.7)	51.9 ± 12.0	58 (81.6)	67 (94.3)	45.1 ± 18.5	23.7 ± 7.2	0	14 (19.7)	ı	ı
Pallota et al. ²⁴	12^{b}	7 (58.3)	5 (41.7)	41.0	10 (83.3)	11 (91.7)	46.7	29.4	$0.41~\mathrm{mg}^\mathrm{c}$	$1.45~\mathrm{mg}^\mathrm{c}$	2.08 ^a	4.17 ^a
Tumino et al. ²¹	102	42 (41.2)	60 (58.8)	51.0 ± 12.5	95 (93.1)	I	51 ± 22.5	ı	I	ı	I	I
Aer-O-Scope												
Vucelic et al. ²⁵	12	11 (91.7) 1 (8.3)	1 (8.3)	30 ± 8	10 (83.3)	10 (83.3)	14	ı	2 (16.7)	ı	ı	ı
Gluck et al. ²⁶	28	34 (58.6)	24 (41.4)	27 to 72 ^d	55/56 (98.2)	52/55 (94.5)	10.6 ± 7.1	13.3 ± 7.6	1	ı	ı	ı
Invendoscope												
Rosch et al. ²⁷	34	19 (55.9)	19 (55.9) 15 (44.1) 49.7	49.7	28 (82.4)	I	ı	ı	27 (79.4)	ı	$1.96^{\rm e}$	ı
Phase 1	24	ı	ı	ı	19 (79.2)	I	26	ı				
Phase 2	10	1	1	ı	(06) 6	I	20	1				
Groth et al. ²⁸	61	34 (55.7)	34 (55.7) 27 (44.3) 57.5	57.5	60 (98.4)	I	15 (7-53.5) ^f	ı	3 (4.9)	ı	1.6^{g}	ı
Neoguide												
Eickhoff et al. ²⁹	11	7 (63.6)	4 (36.4)	11 $7(63.6)$ $4(36.4)$ $43(19 to 80)^d$ $10(100)$	10 (100)	ı	20.5	ı	10 (100)	1	1	ı
	ľ										:	

Studies described were carried out using the SC20 colonoscope with the inverted sleeve mechanism. The most recent SC210 model that received 510 k clearance in 2018 does not describe this mechanism for

^aPain score 0-10 locomotion.

^bPatients with mildly to moderately active ulcerative colitis

^cAverage amount of sedative given

^dAge range of patients

^ePain score 1-6, with 6 being unbearable ^fTime range for cecal intubation ⁸Pain score 1-3, with 6 being unbearable

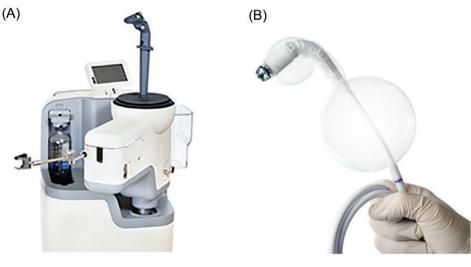
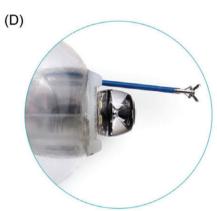


FIGURE 3 A, Aer-O-Scope PC-based work station. B, vision unit and biopsy channel. C, radial joystick steering. D, the Aer-O-Scope colonoscope with the inflated balloons (courtesy and with permission from GI View, Ramat Gan, Israel) [Color figure can be viewed at wileyonlinelibrary.com]





cable supplies electrical, air, water, and suction to the endoscope and the scanning balloon connects to the external workstation. The scanning balloon is shaped like an hour-glass and is designed to conform to the shape of the colon as it navigates. The pressures of the balloons are monitored with electronic sensors adjusted by a computerized algorithm that prevents maximum colonic pressure from exceeding 60 mbar. An optical head at the distal end of the endoscope houses a high-definition digital camera with a 57° field of view and a complete 360° omnidirectional view. An overlaying transparent dome encases the lens and the light emitting diodes (LEDs) that provide the illumination. The propulsion of the scanning balloon is achieved by carbon dioxide, which minimizes the need for the operator to exert a pushing force, greatly facilitating its navigation through the flexures and colonic angulations.²⁶ On withdrawal of the scope the pressures are reversed, which pushes the balloons back towards the rectum. A steerable bending section at the tip of the scope is controlled using a joystick at the workstation.

A feasibility study was first conducted in pigs using 2 prototypes that varied in the length of the supply cable, the diameter of the scanning balloon, and the design of the rectal introducer. The study, conducted using 20 pigs, showed that the maximum insertion of the length of the scope was reached in an average of 84% of the procedures with an average maximum time to insertion of 8.9 ± 4.4 min,

demonstrating that the device was safe and efficient to use in pigs.³¹ In the same year the device was evaluated in a pilot study with 12 human participants. Cecal intubation was achieved in 10 participants. In the remaining 2 participants the scope was unable to pass the hepatic flexure due to a redundant colon in one participant and great pain in the other, which was too great for the procedure to continue. The average time to cecal intubation was 14 min, with a withdrawal time of 3 min. However, as the objective was not to evaluate visualization of the colon, no attentive examination was conducted. Mild petechial lesions, as seen using conventional colonoscopy, were observed and no major complication was reported.²⁵ Controlled steerability for simple navigation and center control was done in a live porcine model. Beads were surgically sewn and implanted into the colons of 12 pigs to simulate polyps. Endoscopists were blinded to the implanted beads and a back to back colonoscopy was performed using the Aer-O-Scope and a conventional colonoscope. The total number of beads detected by the Aer-O-Scope was 94.9%, compared with 86.8% for the conventional colonoscope. The miss rates for beads larger or equal to 6 mm were 2.6% and 10.5%, whereas for beads less than 6 mm, the reported miss rates were 6.9% and 15.1%. respectively. The results of the study proposed that the 360° omnidirectional viewing capacity was superior to that of a conventional colonoscope.³⁰ The efficacy of the device was evaluated in a clinical

study involving 58 participants who presented for CRC screening. Cecal intubation was achieved in 98.2% of the participants, and one patient failed due to inadequate bowel preparation. The detection rate for a polyp was 87.5% in a tandem conventional colonoscopy.²⁶ In September 2016, GI View received clearance for the US Food and Drug Administration 510(k). In that release, the colonoscope is now equipped with an access for therapeutic intervention.

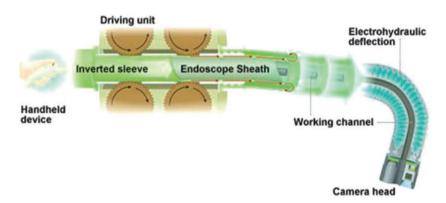
6 | INVENDOSCOPE

Another approach to reducing pain and discomfort to the patients undergoing a colonoscopy is the development of the Invendoscope. This flexible colonoscope was developed by Invendo Medical in Germany and acquired by Ambu (Ballerup, Denmark) in October 2017. The invendoscopy E200 system consists of 3 components; a sterile single-use disposable invendoscope and a reusable handheld control and a processing unit.²⁸ The Invendo SC20 is a computer-assisted

colonoscope propelled by an inverted-sleeve mechanism, Figure 4 shows the propelling mechanism. The colonoscope has a working length of 210 cm and has a tip that can be deflected at 180° in all directions. The vision system consists of 3 white-light LEDs and is equipped with an advanced complementary metal-oxide-semiconductor imaging chip for image visualization. Standard functions including suction, irrigation, and insufflation are also provided, along with a 3.1-cm working channel for a biopsy instrument. The insertion tube is covered by several layers of sheath. The outermost layer covers a double layer of an inverted sleeve that provides the propulsion mechanism.²⁸ The colonoscope is designed to reduce the force exerted on the colonic wall with the aim of reducing patients' discomfort.

The use of the Invendoscope has been examined in 2 published clinical studies. In 2008 a study was performed to determine its feasibility in a group of volunteers. The pilot study consisted of 39 healthy paid volunteers (19 men, 20 women). No sedation was given and the rate of cecal intubation was the primary outcome.²⁷ Two prototypes

FIGURE 4 Schematic representation of the propulsion mechanism of the Invendoscope (adopted from Seah et al³⁴, 2017). The Invendoscope SC200 (adopted with permission from Kurniawan et al³⁶, 2017) [Color figure can be viewed at wileyonlinelibrary.com]





were evaluated, with a main difference in the length of the colonoscope, 170 and 180-200 cm, and a difference in the stiffness in the device tip in the longer colonoscope. Five examinations were terminated prematurely due to defects in the instrument. Of the remaining 34 cases, cecal intubation was achieved in 28 (82%). Five failed cases were encountered, with 2 reporting significant pain at the sigmoid colon. There were fewer failed cases in the prototype with a longer length and a modified tip. In terms of patients' acceptance, which included pain and tolerance, the average score was 1.96 (ranked 1-6, with 6 being unbearable). The mean time to reach the cecum was 26 min for prototype 1 and 20 min for prototype 2. In subsequent a single-arm prospective study²⁸ that was conducted in 2011, healthy paid volunteers were recruited to undergo a screening colonoscopy. A total of 61 volunteers (34 men, 27 women) were enrolled with a mean age of 57.5 years (range: 50-70 y). Cecal intubation was achieved in 98.4% of patients, apart from one participant where the furthest point reached was the ascending colon. In over 60% of the patients, abdominal pressure and a change in the patient's position helped to advance the colonoscope. The average time to reach the cecum was 16.4 min and similarly for withdrawal. Likewise, as in their previous study, the patients' perception of pain and discomfort was recorded. Ranked scores between 1 and 6 were used, with a higher score indicating a worse outcome. The overall assessment for pain was 1.6 and for discomfort it was 2.3. Of the 61 patients, 95.1% underwent a sedationfree complete colonoscopy procedure. In terms of polyp detection, a total of 36 polyps were identified from the participants, with sizes ranging from 2 to 18 mm (mean 4.8 mm). However, 3 polyps from 2 participants were not found again on colonoscope withdrawal. As part of the new invendoscopy E200 system, the invendoscope SC200 is a sterile and single-use colonoscope. The company announced it had received the CE Mark certification from the European Economic Area in December 2016. In October 2017, Invendo Medical was acquired by Ambu, who was already operating in the field of pulmonary endoscopy, and later at the beginning of January 2018, Ambu announced it had been granted US Food and Drug Administration clearance of the invendoscopy system E210 and the invendoscope SC210, a successor of the E200 system and SC200, the difference being the instrument channel diameter was increased to 3.2 mm from 3.1 mm.

7 | NEOGUIDE ENDOSCOPY SYSTEM

The NeoGuide endoscopy system (Neoguide Endoscopy System, Los Gatos, CA, USA) is a computer-assisted colonoscope that has been designed to assume the natural shape of the colon and to travel along the curvature. Utilizing computerized mapping generated in real time as the distal tip advances, it can result in less unintentional lateral force applied to the colon wall. The system uses a programmable overtube and 3-D mapping that provides position viewing of the colonoscope and can effectively reduce and prevent the formation of loops, hence the colonoscopy can be conducted without the use of sedation.³²

The NeoGuide endoscopy system (Figure 5) was developed in 2001. It is held by a support arm that extends from the console, bearing most of the weight of the endoscope. It consists of 16 segments that are independently articulated from each other. The endoscope has an instrument channel with a diameter of 3.2 mm and tapers from a diameter of 14 mm from the tip to 20 mm at the proximal shaft of the colonoscope.²⁹ The first segment has a position sensor and measures the tip steering commands of the endoscopist while another external sensor, which is placed in close proximity to the patient, measures the insertion depth of the colonoscope. As the colonoscope is advanced inside the colon, the tip position sensor conveys the steering commands of the endoscopist to the external sensor which continuously provides data about the scope insertion depth to the actuation controller and provides a real-time 3-D image in the position of the endoscope inside the colon to the endoscopist. The actuation controller automatically articulates each of the segments, allowing for a snaking pattern of the endoscope that moves in a follow-the-leader manner (the active mode) to negotiate colonic flexures. Based on this manner of locomotion, conventional pushing of the endoscope against the colon wall is not required.

An in vitro evaluation of the force exerted by the NeoGuide endoscope was conducted, first using a synthetic inanimate flexible colon model made from urethane segments. The sections were embedded with gauge-force sensors to measure the force on the colonic wall. In the second part of the study, a human colon model was used. The results showed that the force exerted by the NeoGuide was significantly lower in the inanimate colon model and the mean colonic displacement using the human model compared with a conventional colonoscope (Olympus CF140, Tokyo, Japan).³³

The feasibility and efficacy of this system was also tested in a clinical study. The trial was a prospective, randomized, unblinded study consisting of 11 patients. Altogether 4 women and 7 men were recruited but 1 patient was excluded due to unsatisfactory bowel cleansing. Two end-points were evaluated. The primary end-point was an assessment of safety and the second was effectiveness. No adverse events were seen and no mechanical damage to the colonic wall was observed. A post-procedural assessment performed at 48 hours and 30 days revealed no complications. The procedure was conducted by 3 physicians with varying levels of experience. The patients were offered sedation for pain management. In this small human study, the cecum was reached in all 10 patients, with an overall procedure time, including therapeutic invention, of 34 min (range: 24-60 min). A looping rate of 40% was reported to be extensive in 3 of the 4 cases and it was successfully reduced with the assistance of the computerized 3-D mapping images, demonstrating that the NeoGuide endoscopy system was able to provide information to the position of the tip, the insertion position, and looping in the colon. Approval of the system from the US Food and Drug Administration was obtained in 2006 and the system was acquired by Intuitive Surgicals (Sunnyvale, CA, USA) in 2009.32

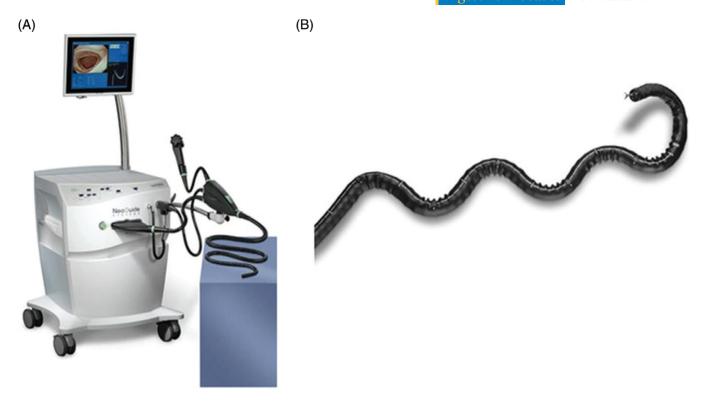


FIGURE 5 A, NeoGuide Endoscopy System. B, multi-segmented insertion tube (adopted with permission from Peters et al³⁷, 2018) [Color figure can be viewed at wileyonlinelibrary.com]

8 | CONSIS MEDICAL

Consis Medical (Beer'Sheva, Israel) was founded in 2016 as a spin-off from IBEX Technologies. This semi-disposable, single-use colonoscope functions with a self-propelling design that propels the inflated sleeve along the intestine. A floating electro-optical unit is mounted in the front of the endoscope that facilitates its insertion and maneuvering inside the colon. At the end of the procedure, the device head, which works like a Pill-Cam can be removed and sterilized while the disposable sleeve cartridge is replaced for the next patient. The multi-use head at the distal portion of the colonoscope includes the camera, light source, air/water nozzle, working channel and the steering system. The body tube is an inverted sleeve that is integrated to the mutli-use head and propelled by pressurized water. The prototype was reported to have undergone tests using human colon simulations and animal tests and clinical tests performed towards the end of 2018.

9 | INNOVATIVE SINGLE-USE ROBOTIC COLONOSCOPE

The key features of this robotic colonoscopic system by NISI, Hong Kong include a tendon-driven active bending mechanism that allows an omnidirectional bending of the colonoscope towards areas of interest while performing the procedure, a twin-balloon anchoring mechanism that provides secure anchorage of the colonoscope to the

colonic wall and thereby acts to straighten the colonoscope to reduce loop formation and/or entanglement and redundancy of the colon so that unobstructed advancement of the colonoscope is possible, the twin-balloon can also act as a flange to expand mucosal folds to reveal lesions that are hidden behind the haustral folds, a flexible and a slender body tube that glides smoothly and an endoscopic 3-D high-definition unit that enables 180° visualization to provide a clear view of the colonic wall. The colonoscope is single use and disposable, and thus it can avoid the need for expensive sterilization or high costs incurred by the need to reprocess it. More importantly, it eliminates all the risks of cross-infection that can arise in between patient use as well as ineffective and incomplete sterility. The functionality and effectiveness of the locomotion mechanism to reach cecal intubation are currently undergoing studies in human cadavers with plans for clinical trials in 2019.

10 | CONCLUSIONS

Robot-assisted colonoscopy systems have advanced to automated designs that are softer and more slender and are focused on reducing the distension of the colon, the formation of loops and, in the worst case, perforation, and thus minimizing the need for endoscopists to use forceful pushing to advance the colonoscope inside the colon, ultimately increasing comfort for both patients and endoscopists. An ideal solution to eliminate contamination risks to patients is to adopt single-use colonoscopes that are sterile straight from the manufacturer's package to the patient. Not only will this provide wider

accessibility to patients of a more personalized diagnostic and treatment plan, easing their health concerns, it can also improve the hospital workflow. Together with an increasingly ageing population, the primary users of surgical services are expected to double by 2060. The use of medical robotics should enable less experienced endoscopists to perform this procedure easing the burden in the long term.

CONFLICT OF INTERESTS

Chung-Kwong Yeung is the chairman and chief technology officer of Bio-Medical Engineering (HK) Limited, Jo LK Cheung and Biji Sreedhar are employees of Bio-Medical Engineering (HK) Limited.

ORCID

Chung-Kwong Yeung https://orcid.org/0000-0002-6526-9305

REFERENCES

- International Agency for Research on Cancer. Cancer Today Globocan 2018. Colorectal cancer. http://gco.iarc.fr/today/fact-sheets-cancers. Accessed January 18, 2019.
- Arnold M, Sierra MS, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global patterns and trends in colorectal cancer incidence and mortality. Gut. 2017;66(4):683-691.
- Shah SG, Pearson HJ, Moss S, Kweka E, Jalal PK, Saunders BP. Magnetic endoscope imaging: a new technique for localizing colonic lesions. *Endoscopy*. 2002;34(11):900-904.
- Marshall JB, Barthel JS. The frequency of total colonoscopy and terminal ileal intubation in the 1990s. Gastrointest Endosc. 1993;39(4): 518-520.
- Shah HA, Paszat LF, Saskin R, Stukel TA, Rabeneck L. Factors associated with incomplete colonoscopy: a population-based study. *Gastroenterology*. 2007;132(7):2297-2303.
- Villa NA, Pannala R, Pasha SF, Leighton JA. Alternatives to incomplete colonoscopy. Curr Gastroenterol Rep. 2015;17(11):43.
- Halpern Z, Gross SA, Gralnek IM, et al. Comparison of adenoma detection and miss rates between a novel balloon colonoscope and standard colonoscopy: a randomized tandem study. *Endoscopy*. 2015; 47(3): 238-244.
- De Palma GD, Giglio MC, Bruzzese D, et al. Cap cuff-assisted colonoscopy versus standard colonoscopy for adenoma detection: a randomized back-to-back study. Gastrointest Endosc. 2018;87(1):232-240.
- Dik VK, Gralnek IM, Segol O, et al. Multicenter, randomized, tandem evaluation of EndoRings colonoscopy - results of the CLEVER study. Endoscopy. 2015;47(12):1151-1158.
- Ponte A, Pinho R, Rodrigues A, et al. High efficacy of repeating colonoscopy by an advanced endoscopist after an incomplete colonoscopy. GE Port J Gastroenterol. 2018;25(6):285-290.
- Gawron AJ, Veerappan A, Keswani RN. High success rate of repeat colonoscopy with standard endoscopes in patients referred for prior incomplete colonoscopy. BMC Gastroenterol. 2014;14:56.
- Rex DK. Risks and potential cost savings of not sending diminutive polyps for histologic examination. Gastroenterol Hepatol. 2012;8(2): 128-130.
- Ofstead CL, Wetzler HP, Heymann OL, Johnson EA, Eiland JE, Shaw MJ. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: results of visual inspections, biochemical markers, and microbial cultures. Am J Infect Control. 2017;45 (2):e26-e33.
- Ofstead CL, Heymann OL, Quick MR, Eiland JE, Wetzler HP. Residual moisture and waterborne pathogens inside flexible endoscopes:

- evidence from a multisite study of endoscope drying effectiveness. Am J Infect Control. 2018;46(6):689-696.
- Neves MS, da Silva MG, Ventura GM, Cortes PB, Duarte RS, de Souza HS. Effectiveness of current disinfection procedures against biofilm on contaminated GI endoscopes. *Gastrointest Endosc.* 2016;83 (5):944-953.
- Gaglia A, Papanikolaou IS, Veltzke-Schlieker W. New endoscopy devices to improve population adherence to colorectal cancer prevention programs. World J Gastrointest Endosc. 2010;2(7):244-251.
- Eliakim R, Yassin K, Niv Y, et al. Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. *Endoscopy*. 2009;41(12):1026-1031.
- Obstein KL, Valdastri P. Advanced endoscopic technologies for colorectal cancer screening. World J Gastroenterol. 2013;19(4):431-439.
- Cater D, Vyas A, Vyas D. Robotics in colonoscopy. Am J Robot Surg. 2014;1(1):48-54.
- Dehghani H, Welch CR, Pourghodrat A, et al. Design and preliminary evaluation of a self-steering, pneumatically driven colonoscopy robot. J Med Eng Technol. 2017;41(3):223-236.
- Tumino E, Parisi G, Bertoni M, et al. Use of robotic colonoscopy in patients with previous incomplete colonoscopy. Eur Rev Med Pharmacol Sci. 2017;21(4):819-826.
- 22. Cosentino F, Tumino E, Passoni GR, Morandi E, Capria A. Functional evaluation of the endotics system, a new disposable self-propelled robotic colonoscope: in vitro tests and clinical trial. *Int J Artif Organs*. 2009;32(8):517-527.
- Tumino E, Sacco R, Bertini M, Bertoni M, Parisi G, Capria A. Endotics system vs colonoscopy for the detection of polyps. World J Gastroenterol. 2010;16(43):5452-5456.
- Pallota S, Tumino E, Manes G, et al. Assessment of ulcerative colitis endoscopic activity with a novel robotic colonoscope: the endotics endoscopoy system. *Dig Live Dis*. 2011;43(suppl 3):S199. https://doi. org/10.1016/S1590-8658(11)60383-6.
- 25. Vucelic B, Rex D, Pulanic R, et al. The Aer-O-Scope: proof of concept of a pneumatic, skill-independent, self-propelling, self-navigating colonoscope. *Gastroenterology*. 2006;130(3):672-677.
- Gluck N, Melhem A, Halpern Z, Mergener K, Santo E. A novel selfpropelled disposable colonoscope is effective for colonoscopy in humans (with video). Gastrointest Endosc. 2016;83(5):998-1004.e1.
- Rösch T, Adler A, Pohl H, et al. A motor-driven single-use colonoscope controlled with a hand-held device: a feasibility study in volunteers. Gastrointest Endosc. 2008;67(7):1139-1146.
- Groth S, Rex DK, Rösch T, Hoepffner N. High cecal intubation rates with a new computer-assisted colonoscope: a feasibility study. Am J Gastroenterol. 2011;106(6):1075-1080.
- Eickhoff A, van Dam J, Jakobs R, et al. Computer-assisted colonoscopy (the NeoGuide Endoscopy System): results of the first human clinical trial ('PACE study'). Am J Gastroenterol. 2007;102(2):261-266.
- Gluck N, Fishman S, Melhem A, Goldfarb S, Halpern Z, Santo E. A novel colonoscope with panoramic visualization detected more simulated polyps than conventional colonoscopy in a live swine model. *Endosc Int Open*. 2015;3(6):E642-E645.
- Pfeffer J, Grinshpon R, Rex D, et al. The Aer-O-Scope: proof of the concept of a pneumatic, skill-independent, self-propelling, selfnavigating colonoscope in a pig model. *Endoscopy*. 2006;38(2): 144-148.
- Peters BS, Armijo PR, Krause C, Choudhury SA, Oleynikov D. Review of emerging surgical robotic technology. Surg Endosc. 2018;32(4): 1636-1655.
- Eickhoff A, Jakobs R, Kamal A, Mermash S, Riemann JF, van Dam J. In vitro evaluation of forces exerted by a new computer-assisted colonoscope (the NeoGuide endoscopy system). Endoscopy. 2006;38(12): 1224-1229.
- 34. Seah TET, Do TN, Takeshita N, Ho KY, Phee SJ. Future of flexible robotic endoscopy systems. arXiv preprint arXiv:170305569. 2017.

- 35. Yeung BP, Chiu PW. Application of robotics in gastrointestinal endoscopy: a review. World J Gastroenterol. 2016;22(5):1811-1825.
- 36. Kurniawan N, Keuchel M. Flexible gastro-intestinal endoscopy clinical challenges and technical achievements. *Comput Struct Biotechnol J.* 2017;15:168-179.
- 37. Peters BS, Armijo PR, Krause C, Choudhury SA, Oleynikov D. Review of emerging surgical robotic technology. *Surg Endosc.* 2018;32(4): 1636-1655.

How to cite this article: Yeung C-K, Cheung JL, Sreedhar B. Emerging next-generation robotic colonoscopy systems towards painless colonoscopy. *J Dig Dis.* 2019;20:196–205. https://doi.org/10.1111/1751-2980.12718